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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
08/852,495	05/07/97	RUDDY	D	17957-000110

HM12/0731

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EXAMINER	
VANDER VEGT,F	
ART UNIT	**PAPER NUMBER**
1644	23

DATE MAILED: 07/31/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/852,495	Applicant(s) Ruddy et al
	Examiner F. Pierre VanderVegt	Group Art Unit 1644

☒ Responsive to communication(s) filed on *May 22, 2000* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *29-48* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *29-48* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application is a continuation-in-part of application S.N. 08/724,394, which is a continuation-in-part of application S.N. 08/630,912, which is a continuation-in-part of application S.N. 08/652,265.

Claims 29-48 are currently pending in this application.

Continued Prosecution Application

1. The request filed on May 22, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/852,495 is acceptable and a CPA has been established. An action on the CPA follows.

2. In view of the amendment filed May 22, 2000, no outstanding rejections are maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 37-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,872,237 to Feder et al (A1 on form PTO-892). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed nucleic acid sequence of the '237 patent is the same as the

full length sequence of the instant claims and therefore contains all the polymorphic sites listed in the instant Table 1. The sequence claimed '237 patent is therefore an anticipatory sequence of the instantly claimed genus.

4. Claims 29-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,872,237 (A1) in view of Campbell (U1).

The '237 patent has been disclosed supra. Campbell teaches that "[i]t is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)" (page 29, section "Basic research" in particular). One of ordinary skill in the art at the time the invention was made would have readily recognized theat the ~235 kilobase sequence of the '237 patent contains the coding regions of at least several genes, as evidenced by the presence of multiple poly-T regions within the sequence within the sequence. It would have been prima facie obvious to that artisan to create primer sequences based upon the sequence claimed in the '237 patent in order to amplify and clone the potential coding regions. One would have been motivated, with a reasonable expectation of success, to amplify and clone the potential coding regions using paired primers based upon the sequence claimed in the '237 patent due to the fact that it is a conventional practice in the art to do so for further study, characterization and identification of proteins coded for by said regions. It is respectfully submitted that expression of polypeptides in both prokaryotic and eukaryotic vectors were well within the purview of the artisan at the time the invention was made.

Claim Rejections - 35 USC § 112

5. Claims 29-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Summarizing the ranges claimed in base claims 29, 33, 37 and 41, the claims are drawn to nucleic acid sequences of various sizes ranging from at least 8 bases up to about 235 kilobases. Said sequences do not specify any particular start or end points limited only by that they must comprise a sequence of consecutive bases of SEQ ID NO: 1 or 2 of at least 8 bases up to about 235 kilobases and that they must contain at least one of the polymorphic sites listed in Table number 1 of the instant specification. The written description in this case only sets forth the nucleic acid sequences of SEQ ID NO: 1 & 2 and the polymorphic sites of Table 1. Therefore the written description is not commensurate in scope with the claims drawn to the full genus of nucleic acid molecules encompassed by recitations of "comprising at least 8 consecutive bases" and "up to about 235 consecutive kilobases" of SEQ ID NO: 1 or 2.

Vas-Cath Inc. v. Mahurkar ((CAFC, 1991) 19 USPQ2d 1111), clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See *Vas-Cath* at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see *Vas-Cath* at page 1115).

With the exception of the sequences defined by SEQ ID NO: 1 and 2, the skilled artisan cannot envision the detailed structure of the encompassed nucleic acid sequences comprising fragments of SEQ ID NO: 1 and 2, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, ((CAFC, 1993) 25 USPQ 2d 1601) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*,((CAFC, 1991) 18 USPQ2d 1016).

Furthermore, In *The Reagents of the University of California v. Eli Lilly* ((CAFC, 1997) 43 USPQ2d 1398), the court held that a generic statement which defines a genus of nucleic acids

without distinguishing that genus from others, except by their function, does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention."

Therefore, nucleic acid molecules consisting of fragments of SEQ ID NO:1 or SEQ ID NO:2 comprising at least one of the polymorphic sites of Table 1, but not the full breadth of the claims generically drawn to comprising said fragments, meet the written description provision of 35 USC 112, first paragraph as provided by the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the Applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the Applicant for patent.

6. Claims 29, 33, 45 and 46 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cornall et al (V1).

The Cornall et al reference teaches a 97 base oligonucleotide comprising positions 1-39 of SEQ ID NO: 1 and further comprising the polymorphic site of Table 1 located at nucleotide position 35-36. Applicant is reminded that the term "comprising" recited in claims 29 and 33 is open-ended. It would open up the sequences to include other residues within the recited size range comprising said sequences. The prior art teaching clearly anticipates the claimed invention.

7. Claims 29, 33, 45 and 46 are rejected under 35 U.S.C. 102(a,e) as being clearly anticipated by U.S. Patent No. 5,582,979 to Weber (B1).

The '979 patent teaches a 44 base oligonucleotide, SEQ ID NO: 249, comprising positions 1-38 of SEQ ID NO: 1 and further comprising the polymorphic site of Table 1 located at nucleotide position 35-36. The '979 patent further teaches a 56 base oligonucleotide, SEQ ID NO: 149, comprising positions 32512-32559 of SEQ ID NO: 1 and further comprising the polymorphic site of Table 1 located at nucleotide position 32556-32559. Applicant is reminded that the term "comprising" recited in claims 29 and 33 is open-ended. It would open up the sequences to include other residues within the recited size range comprising said sequences. The prior art teaching clearly anticipates the claimed invention.

8. Claims 29, 33, 45 and 46 are rejected under 35 U.S.C. 102(a,e) as being clearly anticipated by U.S. Patent No. 5,719,125 to Suzuki et al (C1).

The '125 patent teaches a 60 base oligonucleotide, SEQ ID NO: 11 comprising positions 53598-53636 of SEQ ID NO: 1 and further comprising the polymorphic site of Table 1 located at nucleotide position 53631-53637 [sic]. The poly-T region of SEQ ID NO: 11 of the '125 patent further comprises the polymorphic sites of Table 1 located at nucleotide positions, 178551-178552, 214529-214530 and 225366-225367. Applicant is reminded that the term "comprising" recited in claims 29 and 33 is open-ended. It would open up the sequences to include other residues within the recited size range comprising said sequences. The prior art teaching clearly anticipates the claimed invention.

Conclusion

9. A copy of U.S. Patent No. 5,872,237 to Feder et al (A1 on form PTO-892) has not been included with this Office Action due to the extremely large size of the document (686 pages). The instant Applicants are also named as co-inventors of the '237 patent, which is commonly assigned, and the document is readily available in electronic form in both text and image formats at USPTO's web-based searchable patent database (http://www.uspto.gov/patft/index.html). Printing the document would therefore be an unnecessary use of resources.

10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

11. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2000 366-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

F. PIERRE VANDERVEGT
PATENT EXAMINER

F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
July 21, 2000